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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,176	07/08/2003	Taik Koo Yun	0662-0189P	6452

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EXAMINER	
COE, SUSAN D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 02/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/614,176	YUN ET AL.	
	Examiner	Art Unit	
	Susan Coe	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7-8-03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-6 are currently pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using a composition comprising ginsenoside glycosides to reduce the occurrence of cancer, does not reasonably provide enablement for using this composition to prevent cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are broadly drawn to preventing cancer using a composition comprising ginsenoside glycosides. Claim 2 specifies that the ginsenoside glycosides are selected from ginsenoside Rg3, Rg5, or Rh2. According to the paragraph spanning pages 9 and 10 of applicant's specification, these three ginsenosides are present in any ginseng, particularly

in red ginseng. Thus, a composition of ginseng or red ginseng is considered to be a composition comprising the ginsenoside glycosides Rg3, Rg5, and Rh2. The prior art teaches that ginseng and red ginseng reduce the occurrence of cancers (Yun et al. Cancer Epidemiol. Biomarkers & Prev. (1995), vol. 4, pp. 401-408). Applicant also explains this same study in their specification. Thus, both the prior art and applicant's specification are considered to be enabled for reducing the occurrence of cancer using a composition comprising the ginsenosides Rg3, Rg5, and Rh2. However, neither the prior art nor applicant's specification teaches that a composition comprising ginsenoside glycosides is able to prevent cancer. To be enabled for prevention, applicant must show that the composition comprising the ginsenosides are able to prevent cancer in each and every possible occurrence of the cancer. It is well known that the causes of cancer are widely varied and extremely difficult to predict with complete accuracy. Due to this fact, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if the composition comprising the ginsenosides would be able to function as claimed. This undue experimentation shows that applicant's specification is not enabled for preventing.

In addition, while applicant's claims are not specifically directed to using the isolated ginsenosides Rg3, Rg5, and Rh2 to prevent cancer, please note that applicant's specification is not considered to be enabled for preventing **or** reducing the occurrence of cancer using these isolated ginsenosides. Applicant's specification has small study with rats that does not show a significant reduction in the amount of cancers developed by rats taking the isolated ginsenosides when exposed to a carcinogen compared to rats not taking the isolated ginsenosides. In addition, it is well known in the art that animal models are not considered to be enabling for human

treatment. Furthermore, the prior art only shows that the isolated ginsenosides are able to treat cancer either *in vitro* or in animal models (see references cited below under pertinent prior art).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Yun et al. (Cancer Epidemiol. Biomarkers & Prev. (1995), vol. 4, pp. 401-408).

Applicant's claims drawn to preventing cancer using a composition comprising ginsenoside glycosides. Claim 2 specifies that the ginsenoside glycosides are selected from ginsenoside Rg3, Rg5, or Rh2. According to the paragraph spanning pages 9 and 10 of applicant's specification, these three ginsenosides are present in any ginseng, particularly in red ginseng. Thus, a composition of ginseng or red ginseng is considered to be a composition comprising the ginsenoside glycosides Rg3, Rg5, and Rh2. Yun teaches that ginseng and red ginseng reduce the occurrence of cancers (see page 407, last paragraph). Thus, Yun teaches a method of reducing the occurrence of cancer using a composition comprising the ginsenosides Rg3, Rg5, and Rh2. Yun teaches that more than one ginseng can be consumed to reduce the occurrence of cancer; thus, the reference is considered to teach applicant's claim 3. In addition, Yun teaches that the ginsengs contain amino acids (see page 407, first full paragraph); thus, the reference is considered to teach applicant's claim 6. Furthermore, Yun teaches that vitamins are

also useful in reducing the occurrence of cancer (see page 406, first column, second full paragraph); thus, the reference is considered to teach using vitamins to reduce the occurrence of cancer in addition to the use of ginseng. Finally, Yun does not specifically mention the concentration of ginsenosides in the ginseng composition; however, Yun does teach that the amount of ginseng ingested by the patient can vary (see Table 3). The higher amounts of ginseng intake would contain the amount of ginsenosides claimed in applicant's claim 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yun et al.

As discussed above, Yun does not specifically mention the concentration of ginsenosides in the ginseng composition; however, Yun does teach that the amount of ginseng ingested by the patient can vary (see Table 3). It seems very reasonable to assume that the higher amounts of ginseng intake would contain the amount of ginsenosides claimed in applicant's claim 4. However, even if the amounts specifically taught by Yun do not contain the requisite amount of ginsenosides, a person of ordinary skill in the art would be motivated to increase the amount of ginseng taken by the patient because the reference teaches that the risk of cancer decreases with in a direct relationship with an increased amount of ginseng intake. This increase would yield intakes with the required amounts of ginsenosides.

5. No claims are allowed. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lee et al. (Anticancer Research, (1997 Mar-Apr) 17 (2A) 1067-72); Liu et al. (Life Sciences, (4 Aug 2000) 67/11, 1297-1306) ; Iishi et al. (Clinical and Experimental Metastasis, (1997) 15/6, 603-611); Tode et al. (Journal of Cancer Research and Clinical Oncology, (1993) 120/1-2, 24-26); and Kim et al. (Life Sciences, (June 11, 1999) Vol. 65, No. 3, pp. PL 33-PL 40).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan D. Coe

Susan Coe, Examiner
February 12, 2004